

**Achievement of Market-Friendly Initiatives and Results Program
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Pharmaceutical Research and Conference Presentation
Establishing Globally-Competitive Pharmaceutical
And Bio-Medical Technology Industries in Jordan:
Assessment of Business Strategies
And The Enabling Environment
Final Report

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This report was prepared by Professor Michael P. Ryan, in collaboration with Chemonics International Inc., prime contractor to the U.S. Agency for International Development for the AMIR Program in Jordan.

The government of the Hashemite Kingdom of Jordan has pursued during recent years an ambitious economic reform effort related to accession to the World Trade Organization and conclusion of a bilateral free trade agreement with the United States. Jordan, though modest in economic size and population, is strategically vital to the Middle East region and economy, as the establishment of the permanent home of the World Economic Forum—Middle East at the Dead Sea testifies. A successful economic reform process in Jordan will resonate beyond its borders. Future economic success will depend in part on Jordan's capacity to foster globally-competitive pharmaceutical and bio-medical technology industries in Jordan. The goal should be to establish Jordan as the region's premier pharmaceutical and bio-medical technology industries center. This report assesses business strategies and the enabling environment.

USAID/AMIR and the International Intellectual Property Institute co-sponsor this report with funding assistance from the Pharmaceutical Research and Manufacturers of America and with assistance from the Jordanian Association of Manufacturers of Pharmaceuticals and Medical Appliances, the Jordan Intellectual Property Association, and the Government of the Hashemite Kingdom of Jordan. Professor Michael P. Ryan, PhD, principal investigator, Georgetown University McDonough School of Business and consultant to the International Intellectual Property Institute and USAID/AMIR, and Jillian Shanebrook, MA, MA, project investigator and consultant to the International Intellectual Property Institute, conducted research during 2004 regarding pharmaceutical and bio-medical technological capabilities, industry competition dynamics, and the institutional, legal, and policy enabling environments in Jordan. The researchers investigated global and local industry sector dynamics and change, especially with respect to pharmaceuticals, bio-medical technology, and medical tourism. Secondly and with a focus on conditions for industry success, the investigators obtained industry perspectives on the enabling environment of government laws, policies, and public administration structures and processes, especially with respect to intellectual property and bio-medical regulation. Finally, the investigators considered university and hospital medical and pharmacological research characteristics as aspects of the enabling environment, especially with respect to clinical research organizations and potential bio-medical clustering in Amman. The investigators, from the perspectives of industrial organization economics, law and economics, and technology management and informed by the most up-to-date general research findings and global best practices, recommend strategies for business, government, and the research community. The investigators recommend additional assessment-study and strategy-articulation regarding the government and its facilitating laws, policies, and regulatory practices, and additional assessment-study and strategy-articulation regarding the research community and its institutional foundations for science and technology advancement.

About the Investigators

PROFESSOR MICHAEL P. RYAN began assisting the Jordanian economic reform effort in 1998 when he was asked to assist with the drafting of new patent and plant variety protection laws in support of its accession to the World Trade Organization. In the years since he has lectured frequently in Jordan regarding intellectual property and technology policy and management, e.g., at the invitation of the Higher Council for Science and Technology and the Royal Scientific Society at its technology entrepreneurship conference and at the invitation of the Young Entrepreneurs Association at its annual conference. In cooperation with USAID/AMIR, the US Patent and Trademark Office, and the International Intellectual Property Institute, he established and has lectured at the annual King Abdullah II Intellectual Property Week conference. The IP Week conference involves the software, information technology, pharmaceutical and bio-medical business communities, university researchers, government policymakers and public administrators, and judges who settle intellectual property-based commercial disputes. In 2003 he lectured members of the Ministry of Economics, Palestinian Authority, in Ramallah, West Bank, under auspices of USAID.

Professor Ryan is an associate research professor of policy and ethics at Georgetown University's McDonough School of Business, and a senior consultant to the International Intellectual Property Institute. Professor Ryan established at Georgetown in 1994 the first business and international affairs course in intellectual property management and policy. He is advising and lecturing Thailand's business, government, university, and judicial communities in order to assist with their national bio-medical strategy and is advising and lecturing the countries of the Caribbean regarding their intellectual property-based industries strategies. He has also lectured in Argentina, Brazil, Bulgaria, Chile, China, Croatia, Japan, Malaysia, Peru, the Philippines, Singapore, and South Africa. His *Intellectual Property Management: Business Strategy and Government Policy of Trade Secrets, Patents, Copyrights, and Trademarks* will be published in winter 2005; his co-authored (with Paul Almeida) *Knowledge Strategy: Technology, Intellectual Property, and Organization in the World Economy* will be published in late 2005 as will his *Knowledge Ethics: Intellectual Property and Moral Responsibilities in the World Economy*. He is the author of *Knowledge Diplomacy: Global Competition and the Politics of Intellectual Property* (1998) and *Playing by the Rules: American Trade Power and Diplomacy in the Pacific* (1995). He holds a PhD in political science with concentrations in international political economy, organization, and law from the University of Michigan, holds a master's degree in philosophy from Ohio State University, and previously served on the faculty of the Michigan Business School.

JILLIAN SHANEBROOK, MA, MA, a consultant to the International Intellectual Property Institute, is an economist who specializes in development economics, especially with regard to the economics and institutions of intellectual property-based industries and the role of women in economic development. She and Professor Ryan previously collaborated on a study of international technology management and the MBA curriculum. She served as a Princeton-in-Asia Fellow in Indonesia after earning two

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Summary of Recommendations

RECOMMENDATION 1. LOCAL PHARMACEUTICAL AND BIO-MEDICAL COMPANIES SHOULD PROMOTE EXPORT-ORIENTATION AND/OR MORE TECHNOLOGY-ORIENTATION. CLINICAL RESEARCH ORGANIZATIONS, A FAST-GROWING SUB-SECTOR IN JORDAN, SHOULD SEEK MORE WORK FROM AMERICAN MULTINATIONAL AND SMALLER COMPANIES.

Recommendation 1a. Local companies should build export marketing capabilities.

Recommendation 1b. Local companies should consider global strategic options of organic growth, licensing relationships, joint ventures, mergers, and acquisitions.

Recommendation 1c. Local companies should articulate and execute R&D technology strategies aimed at finding market niches, such as improving formulations or by shifting from pills to injectibles.

Recommendation 1d. Local companies should establish manufacturing quality management programs and become Good Manufacturing Practices certified by USFDA and EMEA.

Recommendation 1e. Local companies with good manufacturing capabilities should consider diversifying into the production and marketing of bio-medical devices.

Recommendation 1f. Clinical Research Organizations should build organizational capacities in order to expand the scale and scope of their activities locally, regionally, and internationally.

RECOMMENDATION 2. MULTINATIONAL AND US-BASED DOMESTIC PHARMACEUTICAL AND BIO-MEDICAL COMPANIES SHOULD PROMOTE BUSINESS PARTNERSHIPS WITH JORDAN-BASED COMPANIES.

Recommendation 2a. Multinational and U.S.-based domestic pharmaceutical and bio-medical companies should establish production partnerships with Jordanian companies.

Recommendation 2b. Multinational and U.S.-based domestic pharmaceutical and bio-medical companies should establish marketing partnerships with Jordanian companies.

Recommendation 2c. Multinational and U.S.-based domestic pharmaceutical companies should establish clinical research partnerships with Jordanian companies.

RECOMMENDATION 3. LOCAL PHARMACEUTICAL AND BIO-MEDICAL COMPANIES SHOULD BETTER MANAGE THEIR INTELLECTUAL PROPERTY ASSETS, ESPECIALLY WITH RESPECT TO TRADEMARKED-BRAND MANAGEMENT AND PATENT AND TRADE SECRET MANAGEMENT.

Recommendation 3a. Local pharmaceutical and bio-medical companies should build better trademarked-brand identities.

Recommendation 3b. Local pharmaceutical and bio-medical companies should manage better their patent portfolios.

Recommendation 3c. Local pharmaceutical and bio-medical companies should manage better their trade secrets.

RECOMMENDATION 4. LOCAL AND MULTINATIONAL PHARMACEUTICAL AND BIO-MEDICAL COMPANIES IN JORDAN SHOULD ESTABLISH CORPORATE SOCIAL RESPONSIBILITY PROGRAMS.

RECOMMENDATION 5. ASSESS AND ARTICULATE STRATEGIES TO IMPROVE GOVERNMENT POLICIES AND ADMINISTRATIVE CAPACITIES REGARDING FOOD AND DRUG ADMINISTRATION, PATENT AND TRADEMARK ADMINISTRATION, AND CUSTOMS REGULATION.

RECOMMENDATION 6. ASSESS AND ARTICULATE STRATEGIES TO IMPROVE UNIVERSITY AND PUBLIC SCIENCE AND TECHNOLOGY RESEARCH AND ENCOURAGE TECHNOLOGY TRANSFER TO AND COMMERCIALIZATION BY THE PRIVATE SECTOR.

Frequently Used Acronyms

AMIR - Achievement of Market Friendly Initiatives and Results Program

APM – Arab Pharmaceutical Manufacturing Company

CRO – Clinical Research Organization

DAD – Dar Al Dawa

EMA - European Medicines Agency

GMP – Good Manufacturing Practices

JAPM – Jordanian Association of Pharmaceutical Manufacturers

JFDA – Jordanian Food and Drug Administration

MENA – Middle East and North Africa

MSD – Merck, Sharp & Dohme

NIH – National Institutes of Health

NSF – National Science Foundation

PhRMA – Pharmaceutical Research and Manufacturers of America

RSS – Royal Scientific Society

UPM - United Pharmaceutical Manufacturing

USAID – United States Agency for International Development

USFDA – United States Food and Drug Administration

WIPO – World Intellectual Property Organization

WTO – World Trade Organization

Findings, Assessment, and Recommendations

RECOMMENDATION 1. LOCAL PHARMACEUTICAL AND BIO-MEDICAL COMPANIES SHOULD PROMOTE EXPORT-ORIENTATION AND/OR MORE TECHNOLOGY-ORIENTATION. CLINICAL RESEARCH ORGANIZATIONS, A FAST-GROWING SUB-SECTOR IN JORDAN, SHOULD SEEK MORE WORK FROM AMERICAN MULTINATIONAL AND SMALLER COMPANIES.

In response to Jordan joining the WTO and the trade agreements with the US and Europe, some local pharmaceutical makers have articulated ambitious, forward-looking business strategies. A few companies are focusing on their export and marketing capabilities in the region and beyond; a few companies are focusing on their bio-medical technology R&D capabilities. All companies in the Jordanian pharmaceutical and bio-medical technology industry should improve their export and marketing capabilities and/or their bio-medical technology R&D capabilities. These strategic actions increase substantially the chances that Jordanian pharmaceutical and bio-medical technology industries will survive—and may even thrive—in the global marketplace. Global competitive forces will bring change to the Jordanian industries, ultimately driving some companies from the marketplace absent decisive strategic and organizational renewal. All Jordanian companies should initiate strategic and organizational renewal oriented around export and marketing capabilities; some Jordanian companies should initiate strategic and organizational renewal oriented around R&D and technological capabilities. Clinical research organizations, a fast-growing sub-sector in Jordan, should seek more work from American and other foreign multinational companies.

Recommendation 1a. Local companies should build export marketing capabilities.

The Arab pharmaceutical industry originated in Egypt in the late 1930s, followed by establishment in Morocco in the 1950s and in Iraq and Jordan in the 1960s (Ministry of Planning, 2003:71). The first Jordanian pharmaceutical company, the Arab Pharmaceutical Manufacturing Company APM, was established in 1962. Dar Al Dawa followed in 1975; Hikma Pharmaceuticals was established in 1978. A number of new entrants appeared in recent years, so that there have been 18 companies in Jordan (until a couple of recent mergers).

The Jordanian pharmaceutical industry can be divided into two distinct groups, the older, pre-1980 large companies and the younger, post-1980 smaller firms. The four oldest companies have long dominated production and sales. Market investment totals \$400 million, including 20 manufacturing facilities and over 4000 employees (Hanan Sboul, JAPM, February 2004). Local companies, according to JFDA data for 2003, produced JD54,904,175 in local sales out of a total marketplace for pharmaceuticals in Jordan of JD211,007,592. Thus, volumes in Jordan are low, which, in the words of one manager, “poses challenges for Jordanian firms.” Perhaps due to the small market size and consequent low volumes, Jordanian companies tend to be export-oriented and, since export-marketing capabilities are difficult to acquire and sustain, this is a source of great

competitive advantage. The Ministry of Planning Competitiveness Team—whose study of the local pharmaceutical sector is recommended reading—reports that some-75% of Jordanian production is exported and that Jordanian firms are the biggest exporters by trade volume in the region. Data for the first six months of 2004 indicate that only clothing manufacturing exports (27.3%) out-rank pharmaceuticals (7.7%) in terms of manufacturing contributions to the economy. The Ministry of Planning's data indicates that exports increased by 30% from 1999 to 2002. These are impressive numbers: They show that Jordanian companies have the potential to thrive in the years ahead.

Global markets for pharmaceuticals and bio-medical products and services are becoming increasingly integrated. Trade barriers are coming down around the world, due to multilateral agreements under the World Trade Organization, minilateral agreements such as NAFTA in North America and Mercosul in South America, and bilateral agreements such as U.S. free trade agreements with Jordan, Bahrain, and Morocco. These industry sectors are highly-regulated markets, however, for reasons of product efficacy, safety, and the political economy of public health, so markets remain fragmented by differing regulatory policies and price controls and likely will remain so for awhile. Nevertheless, the global trend is toward market integration through import liberalization and price de-regulation for reasons of the political economy of the global trading system and of the political economy of international public health. Trade diplomats want market efficiencies and comparative advantages to determine international trade flows in pharmaceuticals; public health advocates want the best achievable access to pharmaceuticals through out the world. Thus, business best practices in Jordan, as elsewhere, over the long-term will articulate and build organizational capacities around international business strategies (Bartlett and Ghoshal, 1998 and subsequent editions; Dunning, 1993 and subsequent editions).

Most exports go to the region, especially Saudi Arabia and Egypt. The potential for export growth in MENA is great, since 90% of pharmaceutical products are imported in Arab countries (Market Africa Mid-East, 2003:1). As a result of the U.S.-led war against Iraq, the Jordanian pharmaceutical industry lost its single largest export market (formerly 28% of export sales). Not only did Iraq's relatively large population provide market size, but the peculiarities of the oil-for-food trade relationship led to relatively high profit margins and relatively low marketing expenses (and the complete absence of promotional budgets). The American reconstruction authority required that drugs sold in the Iraq marketplace meet USFDA certification. Future opportunities in the Iraq market are uncertain, but Jordanian companies may be well-positioned to re-gain their former market positions. Demand for pediatric medicines in MENA offers special opportunities because 30% of the region's population is under the age of 15. Dominance of the MENA regional marketplace should be the goal of the Jordanian industry.

The contributions of export success to the Jordanian economy go beyond manufacturing jobs: Marketing pharmaceuticals requires knowledge about therapies and medicines and localized knowledge about hospitals, clinics, doctors, national regulations, and health payment systems. This kind of knowledge is tremendously valuable and at least as economically important as manufacturing know-how. It is this know-how that

will create competitive advantages for Jordanian firms in the region against competitors based in Egypt and other countries of the region and from competitors based in other countries, such as India, China, Thailand, and even Argentina and Brazil. Competitors based outside the region will increasingly establish MENA market presences and marketing capabilities will offer the best defensive—as well as offensive—weapons.

Five companies dominate this export business—Hikma Pharmaceuticals, Arab Pharmaceutical Manufacturing Company, Dar Al Dawa, Jordanian Pharmaceutical Manufacturing Medical Equipment Company, and United Pharmaceutical Manufacturing Company. The survivors and thrivers among Jordanian firms will likely come from this list. However, there is still time: Other companies can join this list.

Recommendation 1b. Local companies should consider global strategic options of organic growth, licensing relationships, joint ventures, mergers, and acquisitions.

For all Jordanian firms the strategic options include

- organic growth (no links with other firms);
- licensing relationships;
- joint ventures;
- merger/acquisition with other firms, whether local, regional, or multinational.

Senior managers should think carefully about these strategic options and—one way or another—build the organizational capabilities for regional, and ultimately, global competitiveness.

Hikma Pharmaceuticals in 1979 established the first international license relationship, in this case, with a Japanese firm. This initial relationship has led to the licensing of 9 different products from the Japanese firm and has led to the licensing of a similar number of products with companies based in not only Japan but also Korea, Italy, Switzerland, the United Kingdom. About a quarter of Hikma sales now owe to these relationships (Mazen Darwazah, Chairman, Hikma Pharmaceuticals, WIPO conference, May 2004). Jordanian companies have in only the last couple of years established production relationships with American, European, and Japanese firms. For example, APM produces under license for a Japanese company; DAD produces for Pfizer and Novartis; UPM and Advanced Pharmaceuticals produces for several European firms (Hanan Sboul, Jordanian Association of Pharmaceutical Manufacturers, WIPO conference).

That these licensing relationships have been increasing in recent years in Jordan is consistent with business research and theory. Licensing of technology has been increasing by about 10% per year in the United States and by about 18% per year internationally (Kotabe, 1996). Licenses typically are either vertical or horizontal with respect to the marketplace: An owner licenses vertically when it provides the patented know-how or trademarked-brand to firms which then may use or market the invention.

Thus vertical licensing generally intends to carry out a product distribution strategy. An owner licenses horizontally when it provides the patented know-how (and possibly the trademarked-brand: consider Intel's "Intel Inside" microprocessor deals with computer makers) to firms which will provide mutual assistance in the development of products. Thus, horizontal licensing generally intends to carry out a product development strategy.

Hikma exports antibiotics to the British market and has international operations in Portugal and in the United States (through its Westward Pharmaceuticals). United Pharmaceuticals has a recent export deal with a German firm. The emerging Jordanian focus on the U.S. and European markets is an important positive development for the industry, for at least some Jordanian firms should begin to establish market presences in these huge markets. (The MENA region accounts for only 2% of global pharmaceutical sales.) These markets offer tremendous opportunities not only because of their size but also because they already boast the best competition. Jordanian companies that seek to find niches despite the excellent competitors in these markets will bring themselves organizational rewards in terms of competencies and capabilities that can invigorate their organizations and increase the likelihood that MENA and other emerging market opportunities will be seized successfully.

Jordanian firms should consider strategic alliances, joint ventures, and mergers/acquisitions with each other. Organizational capabilities within Jordan should be leveraged and brought to bear especially regarding marketing capabilities. Complementary assets should be brought together. For example, Advanced Pharmaceuticals, a small, young firm established in 1994, is merging with Arab Pharmaceutical Manufacturing Company, Jordan's oldest, most established pharmaceutical company. Advanced brings new products and an EU-certified facility; APM has older products but brings an extensive MENA marketing network. Mergers are, however, difficult to make successful, due to differences in leadership structures, management styles, and corporate cultures. Thus, we suspect that strategic alliances and joint ventures may be more suitable relationships for Jordanian companies.

Jordanian companies should consider links not only with each other but also with companies from the region and beyond. American, European, Japanese, Indian, Chinese, Thai, Argentine, and Brazilian firms should be considered not only competitors but potential collaborators (Hamel and Prahalad, 1994, and in particular Hamel and Prahalad, 1989). The growing marketing capabilities of Jordanian companies in the MENA region offer opportunities to co-market drugs in partnership with foreign companies. We heard many complaints from local Jordanian companies that they expected to receive co-marketing agreements with PhRMA members but that these deals have not been forthcoming. However, Jordanian firms must market themselves to foreign companies, explaining their marketing reach and organizational capabilities with respect to distribution. As one Jordan-based PhRMA member manager remarked, "We really don't know what the local companies marketing capabilities are in the region. They need to sell themselves to us. There might be some win-win co-marketing deals that we could do." The only marketing deal between a PhRMA member and a local Jordanian company is a co-promotion partnership between Eli Lilly and Hikma. It is not mere luck

that has brought Hikma this prized relationship: They have earned it through their business practices. In short, MENA and global market presence should drive strategy at Jordanian companies.

Recommendation 1c. Local companies should articulate and execute R&D technology strategies aimed at finding market niches, such as improving formulations or by shifting from pills to injectibles.

Pharmaceutical and bio-medical industries can be bifurcated into, on one hand, the innovation-based, high technology-driven sectors, including the innovative pharmaceutical sector and the advanced medical devices sector, and, on the other hand, the commodity-based, low-technology sectors, including the markets for generic drugs and medical supplies.

Economists of high-technology, high-innovation industries explain that the business of drug innovation is perhaps the most R&D intensive of any industry sector (Mansfield, 1986; Pakes and Simpson, 1989). Innovative drugs are especially susceptible to the appropriability problem in knowledge-based economic activity. In turning a prospective chemical compound into a drug that may be distributed in the public health system requires some 8 to 12 years of computer modeling, animal-testing, and, finally, clinical trial human-testing, yet the compound itself may often be relatively easily reverse engineered and the actual manufacturing production costs generally are modest as a percentage of innovation costs (DiMasi, 1995). A new drug may not be introduced into the public health marketplace in the United States or Europe until it has been shown by its inventors to be effective and safe. The drug approval regulatory process is administered in the United States by the Food and Drug Administration and in the European Union by the European Agency for the Evaluation of Medicinal Products (Pisano, 2002:854; Cuvillier, 2000:137-156). Under the supervision of FDA or EMEA, many years of laboratory testing are followed by many more years of clinical trials conducted on real patients. Economists of technology innovation put new product development costs in the pharmaceutical industry at about \$400 million in out-of-pocket costs per approved drug and, when the costs of capital and of failed R&D efforts are included in the analysis, total R&D costs amount to about \$800 million per successful drug (Grabowski, 2002:852). The single most costly part of the R&D process is the phase III clinical trial, the human trials, which on average costs about \$86 million.

Since only about one percent of chemical compounds identified as having therapeutic potential emerge from the development and regulatory process (DiMassi, 1995:1-14), not only are the “losers” a non-trivial issue but managerial economists explain that firm size and R&D scope are critical competitive advantages to managing financial capital, risk, and organizational learning opportunities (Henderson and Cockburn, 1994; Henderson and Cockburn, 1996). Hence, a drug needs peak sales of \$500 million per year to justify the investment and the top-selling handful of drugs likely bring in about half of revenues at each of the companies (Grabowski, 2002:852). It is thus a very high risk business akin to being in the business of providing venture capital to

entrepreneurs with uncertain prospects for success. These huge development costs explain why nearly every drug innovated in the modern era has been brought to market by private enterprises (Scriabine, 1999). “The research-intensive pharmaceutical firm is the most effective agency for technological innovation because it is sensitive to and able to respond to the stimuli of all the driving forces; it is especially sensitive to market demand (Achilladelis, 1999:18).

While multinational, innovative pharmaceutical companies invest 12-20% of their annual net sales to R&D, Jordanian firms apparently invest about 0.1% of sales to R&D. Jordanian firms are thereby not very well poised to model themselves after the integrated firms that conduct R&D, get new drug launch approvals, and then market new innovative drugs. Ninety-five percent (some 750 products) of the medicines produced by Jordanian companies are generic, while under-patent drugs produced under license make up the 5% remainder (Market Africa Mid-East, 2003:1-3). The global generic business has been a \$14-15 billion industry but is expected, due to patent expirations and other market changes, to grow to \$32 billion in 2004 (Dougherty, 2002:3). Within the generic therapeutic areas, the majority of Jordanian pharmaceutical companies, however, concentrate production within a small number of product categories. Twelve of the companies produce anti-ulcerants, systemic antibiotics, anti-rheumatic system medications, and non-narcotic analgesics (Ministry of Planning, 2003:76-77). Jordanian companies do have technological capabilities with respect to formulation and stability and bio-equivalence and there are market opportunities for new formulations. Jordanian firms should look outside the crowded therapeutic areas in which they now compete, identify product market opportunities, and make them happen.

For example, Triumpharma creates innovative drug delivery systems by converting off-patent molecules that have side effects and absorption problems into improved patented molecules. This innovation-based business strategy offers the potential for high-margin sales. The CEO of Triumpharma, Dr. Al Ghazawi, recommends this strategy to Jordanian firms because improved drug delivery research presents relatively low barriers to entry (millions rather than billions of dollars in R&D investment), technology management opportunities to pursue parallel R&D projects with more than one product as goal, and relative rapid time to market (3-4 years rather than 10-12).

Another example is Advanced Pharmaceuticals, which is producing injectibles. The managing director, Dr. Rakan Rshaidat, explains its competitive advantage had traditionally been in the reverse engineering and production of in-patent pharmaceuticals and that, when Jordan's patent law reforms and enforcements took that business model away, Advanced turned their R&D capabilities to injectibles. Injectibles are considered a niche market because most competitors produce drugs in solid dosage form and because injectibles have relatively high barriers to entry due to specialized expertise and expensive production capabilities. Advanced now sells these products in Europe because they are certified GMP by EMEA. Thomas Ericsson, the managing director at United, a manager with long experience in the European and U.S. pharmaceutical businesses,

emphasizes that each Jordanian company must find global competitive advantage in a good, smart niche.

Recommendation 1d. Local companies should establish manufacturing quality management programs and become Good Manufacturing Practices certified by USFDA and EMEA.

A number of Jordanian companies (Hikma, United, DAD, Hayat Pharmaceutical Industries, Pharma International, and Advanced Pharmaceutical Industries) have come into compliance with European Union manufacturing standards, so-called “Good Manufacturing Practices” (Asia Africa Intelligence Wire, 2002:1-2). However, only Hikma is certified by USFDA to produce for the American marketplace. What sets the production of pharmaceutical products apart from other manufactured goods are the extensive government regulations regarding high quality control standards. That is, quality manufacturing matters in all industries but in most industries it is a matter of corporate strategy not government regulation. These manufacturing regulations regarding GMP demand that quality be attained through processes that meet standards of Quality Control and Quality Assurance (Bian, 1997:44-45; Spilker, 1989:463).

Quality is usually described in terms of five factors: (1) purity of raw materials, (2) ability of drugs to meet chemical and physical specifications, (3) consistency of product from batch to batch, (4) validation of procedures, and (5) validation of systems (Spilker, 1989:463). The acceptance quality level refers to the highest percentage of defective products that is acceptable. Batches are tested, for example, by disintegration and dissolution characteristics and tablet weight (Spilker, 1989:464). All Jordanian companies should seek to come to be certified by USFDA, EMEA, and Japanese regulatory authorities for production deals depend on such certifications.

Local Jordanian pharmaceutical managers often complain that they have not received the production deals with PhRMA—and especially American—companies that they had expected to receive. But, USFDA and EMEA certification for GMP is a necessary condition for such deals: This is not a matter of, “It really enhances one’s competitive position to be certified GMP.” No, this is a must. Attaining international recognition for GMP is critical to the long-term success of Jordanian companies. The production deals can then happen, but Jordanian companies must know that the regulatory hurdles must be cleared because a poorly manufactured product is ruinous in this business. The Novartis general manager in Amman, Ramzi Tubbeh, said that the packaging deal with DAD is a first step and, as confidence in this relationship grows, he expects the production relationship to grow.

Recommendation 1e. Local companies with good manufacturing capabilities should consider diversifying into the production and marketing of bio-medical devices.

As an increasing number of Jordanian companies gain international recognition that manufacturing capabilities are core competencies to their competitive advantages, some companies should consider more emphasis on bio-medical devices and equipment.

Jordanians should study and perhaps emulate aspects of the Taiwanese national information technology manufacturing strategy. The Taiwanese established special trade zones (Aqaba is such a zone for Jordanians); the government assisted with the identification of potential IT manufacturing licensors by leading trade missions to Silicon Valley, other centers in the United States, and trade shows (the Ambassador in Washington and his staff can assist with this effort where there are regional centers of medical device product innovation and production); Taiwanese companies manufactured under license to U.S. firms, improving their manufacturing capabilities and establishing international awareness; Taiwanese firms then established their own R&D capabilities and trademarked-brand management programs. At least a few Jordanian companies should study the Acer example in Taiwan, a now well-known innovator and maker of computers and related equipment, for lessons that could contribute to similar success stories in the bio-medical devices and equipment business. We offer United Pharmaceuticals as an example of a Jordanian company that has moved its strategy in this direction with production of transdermal patches.

Recommendation 1f. Clinical Research Organizations should build organizational capacities in order to expand the scale and scope of their activities locally, regionally, and internationally.

Perhaps the fastest growing, the most promising, and among the most important areas of bio-medical growth for Jordan is the rapid growth in the clinical research organization sub-sector. Three CROs were established some years ago to assist the Jordanian pharmaceutical industry with bio-equivalence R&D, including the Arab Company for Drug Industries and Medical Appliances (1976), The Royal Scientific Society's Pharmaceutical Research Unit (1993), and the International Pharmaceutical Research Center (1995). The Jordanian Center for Pharmaceutical Research was established in 2001, though has conducted research within the university setting since 1984. Finally, Triumpharma Center has started-up CRO activities in 2004. This is an exciting area of growth for Jordan because they carry out high value-added activity that contributes high-skill jobs, economic growth, and knowledge to Jordan's emerging bio-medical technology cluster.

The International Pharmaceutical Research Center is a useful case study. Dr. Naji Najib had organized bio-equivalence studies beginning in 1988 as a member of the faculty and ultimately dean of the School of Pharmacy at Jordan University of Science and Technology. As market demand for these kinds of services increased, he saw, on one hand, business opportunity and, on the other hand, he realized that academia was not the best organizational setting to do essentially commercial research. As a former Fulbright scholar at the University of Michigan in the U.S., he recognized the opportunities but also the business challenges. He launched his company in 1995 with a few hundred thousand dollars in start-up money and a few employees. By 1997 he went operational--though he points out that it should not have taken so long and blames Jordanian regulatory authorities for slow decision-making that nearly killed the infant enterprise. Three years ago the European authorities, EMEA, certified his research operations as meeting their standards for Good Clinical Practices; this year USFDA similarly has certified his

operations. Today his company operates from a new building, provides research services to companies through out the MENA region, and employees some 70 people, including two PhDs, an MD, and three who hold masters degrees.

In response to improvements in the intellectual property policy environment in Jordan owing to WTO-accession and Jordan-US FTA and to growing bio-medical technological and organizational capabilities in Jordan, multinational innovator companies have established a new clinical research organization industry sector in Jordan and are thereby having a growing technological and economic impact in Jordan. Multinational pharmaceutical companies, including Aventis, Bristol Myers Squibb, Eli Lilly, Janssen Cilag, Merck Sharpe & Dohme, Novartis, Organon, and Pfizer have during the past couple of years carried out clinical trial R&D in partnership with the King Hussein Medical Center and hospitals in Amman. Organon initiated this activity in Jordan when it decided in 2000 to conduct clinical trials for its new fertility therapy in Amman. Bristol-Myers Squibb initiated in 2001 a 3-year, 5000 patient trial to study cardiovascular risk factors in Jordanians.

Four multinational companies are now carrying out 17 clinical trial projects. In 2004 Aventis is conducting six local trials; Pfizer and Novartis are conducting four trials each; MSD is conducting three trials. These clinical trials involve hundreds of patients who are receiving access to innovative, cutting-edge pharmaceutical therapies in the areas of cancer, renal failure, schizophrenia, epilepsy, antibiotics, painkillers, anti-infectives, anti-fungal, dyslapedenia, diabetes, fertility, osteoporosis, osteoarthritis, sepsis, thalassaemia, and cardiovascular disease.

CROs in Jordan should seize the opportunity to expand the scale and scope of their activities domestically, regionally, and internationally. Research-based, innovator pharmaceutical companies based in the U.S. and Europe are under great pressure to reduce clinical trial costs. Large pharmaceutical companies, actively seeking lower-cost markets to conduct clinical trials, may be encouraged by the trial activity that has been taking place in recent years. Smaller pharmaceutical innovator companies, perhaps lacking the resources to undertake clinical trials in the U.S., may welcome the opportunity to continue the R&D process (otherwise licensing to or selling out to a big company) in partnership with Jordanians. Furthermore, generic-makers based in the United States and Europe similarly are looking for opportunities to reduce their bio-equivalence R&D expenses, for their margins will be slimmer in the marketplace than are the innovators. However, Jordanian CROs and hospitals appear to lack the means to help both large and small innovator companies and generic makers as much as they could be. Clinical trial work requires big numbers of patients, so Jordanian CROs and hospitals should increase the scale and scope of their activities locally and regionally. Concomitantly, Jordanian CROs should aggressively seek to market their services in the United States and Europe. Dr. Naji Najib has his sights set on these international market opportunities and so should others.

In particular clinical research contributes important bio-medical technology transfer to the hospital system in Jordan and the hospital system is key to Jordan's

medical tourism strategy. According to the Ministry of Planning's Competitiveness Unit, medical tourism, which dates in Jordan at least to the 1970s, is seen as a growth opportunity. Health services employment has grown 52% since 1997 and health services contributions to GDP rose to 3.5% in 2001 (latest figures available) from 2.8% in 1997. Medical tourism generates about two-thirds of all the tourism income to Jordan. Patient surveys say that the medical expertise of the physicians is the main reason for medical tourism to Jordan and extensive clinical trial work in Jordan's hospitals can only serve to enhance that know-how. If marketed and advertised well, the Jordanian hospital system will receive reputational benefits that will further enhance medical tourism prospects.

RECOMMENDATION 2. MULTINATIONAL AND US-BASED DOMESTIC PHARMACEUTICAL AND BIO-MEDICAL COMPANIES SHOULD PROMOTE BUSINESS PARTNERSHIPS WITH JORDAN-BASED COMPANIES.

Many Jordanians complain that their country has not received foreign direct investment, by which people seem to mean the construction of manufacturing plants, from PhRMA companies. We emphasize that this expectation was ill-conceived from the beginning because of the nature of the product--small, light, expensive product, inexpensively shipped. The Swiss don't make Rolexes or Mont Blanc pens in Jordan either. Absent a trade or regulatory barrier, in general it makes little business sense to invest in manufacturing capacity in Jordan or anywhere else in the region. Such manufacturing investment likely will be the exception rather than the rule—most-everywhere in the world. Nevertheless, there actually is and can be a good deal more business partnerships and investment.

Recommendation 2a. Multinational and U.S.-based domestic pharmaceutical and bio-medical companies should establish production partnerships with Jordanian companies.

Nevertheless, as discussed above, a few Jordanian companies have been able to sell themselves as production partners. Large, innovative, integrated pharmaceutical companies such as Eli Lilly, Merck, and Pfizer find their global competitive advantages in their capacities to carry out the expensive and risky R&D to identify a good therapy, get the therapy approved by regulatory authorities, and, then, distribute it to hospitals and clinics through out the United States, Europe, and beyond. These organizational capacities are difficult to build, so it is not happenstance that the dominant companies in the global business, whether based in the United States, Switzerland, Germany, the United Kingdom, or France, are all around 100 years old. Yet, they do not find their competitive advantages in actually manufacturing the products.

Of course, to sell product, PhRMA companies must first manufacture it. Their products must be manufactured to very high levels of quality due to FDA/EMEA regulatory demands and legal liability in the U.S. marketplace. However, the large international pharmaceutical companies may be willing to move away from

manufacturing, if suitable partners can manufacture product in compliance with GMP and certified as such by FDA and EMEA, in a more cost effective manner. Thus, Jordanian companies should make every effort to comply with GMP, be certified as such, and then market themselves as manufacturing partners to these companies. PhRMA companies should consider production partnerships with Jordanian companies.

Recommendation 2b. Multinational and U.S.-based domestic pharmaceutical and bio-medical companies should establish marketing partnerships with Jordanian companies.

Big, innovative, integrated pharmaceutical companies find competitive advantage in their capacities to introduce new drug therapies to the global marketplace. Previous to 2000, when Jordan's patent regime was weak, a few months after one of these companies launched a new innovative drug, a Jordanian manufacturer would release a copy of it. The local manufacturer in Jordan, thus, would use the innovator's know-how, expensively obtained clinical data, and sometimes even its brochures describing the drug's therapeutic function and side effect concerns. There is no heroism in this kind of business practice: One set of companies steals from another set of companies because it lacks competitive advantages of its own. These circumstances greatly discouraged multinationals from introducing drugs into the Jordanian market. With intellectual property protection, multinationals now are encouraged in Jordan to launch new therapies. For Jordanian citizens, as well as citizens who come to Jordan for medical tourism, this means the best possible drug therapies can become available. For the medical tourism national strategy, this means more reasons for patients to come to Jordan.

The head of operations at Aventis, Hussam Zahieh, explains, "We are much more comfortable in investing in Jordan, for instance in launching expensive drugs to treat osteoporosis. We will take the time and money to create programs for awareness knowing that copycat can't come in and scoop the market." Aventis has launched 6 new products since 2000. The manager from Boehringer Ingelheim, Firas Abu Hayyeh maintains that, prior to 2000, the company would not have made major investments in expensive drug launches for fear of copycats. In 2002, however, the company introduced Spirova, a costly drug used for pulmonary disease, and carried out a big, expensive awareness campaign to encourage its proper use by physicians in Jordan. Since 2000, these companies have greatly expanded their educational programs aimed at improving the standards of medical care and physical education. For example, Merck Sharp & Dohme will this year hold approximately 75 educational programs and academic meetings.

Note that the Aventis manager used the word "invest." These companies find equal measure of their global competitive advantages in marketing and distribution capabilities. A study by the Health Care Financing Administration in the U.S. estimates that drug prices, on average, break down in the following way: costs of chemical inputs=30.1%, marketing and advertising=22.5%; R&D=16%; profits=13%; administration=10%; taxes=8.4%. These companies have established Jordan and sub-region (Iraq, Syria, Lebanon) offices for the distribution of under-patent drugs, hired

marketing staff, and are increasingly thinking of Amman as the center for marketing and distribution activities. Since 2000, employment opportunities for Jordanians have increased dramatically: Pfizer had doubled the number of local employees; Aventis and Novartis have tripled their labor force; Merck Sharp & Dohme has increased its employment by 500%. The way they must conduct marketing and distribution, with sales force training, educational efforts with doctors and health care professionals, and the public, *is* foreign direct investment and contributes more value-added to the Jordanian economy and society than does the actual manufacturing of the medicines. PhRMA companies should launch their most innovative products from “nerve-centers” in Amman.

MENA region marketing capabilities of Jordanian companies are impressive and improving. They proved themselves to be resilient and flexible to the loss of the Iraq market due to the war and to the governance changes that the outcome of the war and its aftermath have produced. PhRMA companies should admire these Jordanian marketing capabilities and take advantage of the opportunities these companies offer to expand marketing partnerships.

Recommendation 2c. Multinational and U.S.-based domestic pharmaceutical companies should establish clinical research partnerships with Jordanian companies.

The amount of clinical research organization activity in Jordan, the number of companies in this new sub-sector, and the number of R&D investments by PhRMA companies being carried out at places such as the King Hussein Medical Center was news to most everyone with whom we spoke except those actually involved in doing it. This is under-appreciated foreign direct investment activity that is a win-win deal for both the PhRMA companies and Jordanians. PhRMA companies should expand clinical trial work partnerships in Jordan.

In short, there are a lot of good business reasons for PhRMA companies to establish and expand partnerships with Jordanian companies. Jordan itself is a small market, but the MENA region is a big one with fast-growing populations that tends to be weighted toward young people. As the population ages in the region, the needs for health care will rise and the opportunities for pharmaceutical makers will similarly rise. PhRMA companies, due to the nature of their industry, tend to have long planning horizons and investing in the Middle East through partnerships with Jordanians makes good long-term business sense.

RECOMMENDATION 3. LOCAL PHARMACEUTICAL AND BIO-MEDICAL COMPANIES SHOULD BETTER MANAGE THEIR INTELLECTUAL PROPERTY ASSETS, ESPECIALLY WITH RESPECT TO TRADEMARKED-BRAND MANAGEMENT AND PATENT AND TRADE SECRET MANAGEMENT.

Business leaders through out the world in all industry sectors increasingly are coming to recognize what companies such as Coca-Cola, Procter & Gamble, and Daimler

have long recognized and what companies such as Apple, Nike, and Sony have more recently concluded: Nothing matters more to the competitive advantage of the company than trademarked-brand management. Drug makers Pfizer, Merck, and Eli Lilly have for 100 years invested in trademarked-brand management and reap the rewards today in the marketplace for their efforts. Their brands are recognized and trusted through out the world and are trademarks valuable to the balance sheets of their companies. Others such as Glaxo Smith Kline, Aventis, and Novartis are old companies that have created new corporate faces and are investing in re-building their brands and trademarks. Few Jordanian companies—in any industry, but especially in pharmaceuticals—have come to this recognition about their trademarked brands—despite claims to the contrary.

Recommendation 3a. Local pharmaceutical and bio-medical companies should build better trademarked-brand identities.

Brand management is largely about building brand identity (Upshaw, 1995). Brand management is an exercise in applied consumer psychology: It is all about what the customer thinks (or believes) about the brand. A bank wants its brand to engender security and trust; a fashion label wants its brand to signal a particular personal style; a drug company wants its brand to signal innovation yet safety. It should invoke in the patient the belief that taking the drug will likely improve his or her state of health, and that there is little risk his or her state of health will actually be worsened by the drug.

A trademark is a word or words, a number or character, a picture or a symbol or a graphic design, or a sound or some combination of these elements, that an enterprise uses to identify its goods or services and distinguish them from those of others. Trademarks convey information to consumers and provide incentives to producers to establish good will in the marketplace (Landes and Posner, 1987). A trademark strategy is essential to brand management.

Trademark rights are conferred by usage; “usage” in this context means placing goods in the marketplace. A trademark becomes a registered trademark through processes administered by national trademark authorities and international trademark authorities in Geneva and the World Intellectual Property Organization. A trademark owner must continue to take action to maintain trademark rights, including use of the mark in commercial activity, carry out proper licensing practices, enforce rights against infringement, and renew registration periodically. As a matter of business strategy, as well as (potential) legal strategy, trademark owners are encouraged to strengthen their marks through deliberate marketing strategies in order to deter conflicts with competitors and succeed when conflicts occur.

A trademark is measured by its “distinctiveness” and a distinctive trademark is capable of identifying the source of goods. There are four categories of trademarks; 1) “generic,” which earns no trademark rights; 2) “descriptive,” which can earn trademark rights if sufficiently distinctive; 3) “suggestive,” which tends to be distinctive; and 4) “arbitrary or fanciful” marks, which are presumed to be by nature inherently distinctive.

A distinctive trademark carries “secondary meaning,” i.e., establishes in the minds of consumers an association with a particular producer, through long and exclusive use in commerce. Numbers (BMW’s 3 series automobiles), colors (IBM’s blue), sounds (MCI’s tone), smells (there actually are a few), and other symbols can acquire secondary meaning. Proper names (Eli Lilly, Merck) and geographic names (Pontiac, the General Motors brand) can through the acquisition of secondary meaning overcome the reluctance in trademark law to grant usage rights to an individual’s name or to a geographic name.

Trade dress is the manner in which a good is presented for sale and can be a trademark. Like a trademark, trade dress merits rights and protections if it is either inherently distinctive in the “combination of elements and the total impression that the dress gives the observer,” in the words of one American judge, or has acquired secondary meaning. However, a trade dress which has become commonplace among competitors in a particular market sector may be seen to have become generic and thereby loses its trademark status. In the pharmaceutical business, trade dress rights apply to the packaging of the product, especially the way the box is designed graphically, but intriguingly by distinctive design of the pill itself, such as the well-known “purple pill” heartburn/reflux medicine.

American and European pharmaceutical companies invest a great deal into trademarked-brand management. Despite claims to the contrary by Jordanians, the local industry does not invest in trademarked brand-management or, at least, does not invest wisely. One need only consider the company names, which tend to lack inherent distinctiveness and to be (rather boringly) descriptive. This situation may not have mattered very much when the Jordanian market was the main place to be doing business, but it considerably weakens competitive advantage when the market opportunities are in the MENA region, Europe, and the United States. Jordanian company senior managers should focus a great deal of their time and energy on trademarked-brand management.

Recommendation 3b. Local pharmaceutical and bio-medical companies should better manage their patent portfolios.

Jordanian pharmaceutical companies traditionally were free riders on the global patent system, but no more. An increasing number of pharmaceutical makers in Jordan now have innovations to protect. For example, Jordan Pharmaceutical Manufacturing Company says it owns eight patents thanks to its focus on R&D. That calls for a deliberate patent management strategy. The patent law reforms carried out by the government of Jordan may have looked at the time as one of the costs of the benefits of WTO accession, but it can be seen now for what it was at that time—a tool of business strategy for forward-looking, ambitious Jordanians.

With the patent right a government confers to an inventor the exclusive right to make, manufacture, distribute, and license to distribute the invention. The patent is an intellectual property right: Property rights, depending on how they are designed and enforced by the state, encourage or discourage productive investment and savings. “In particular,” and critical to the presence or absence of economic growth over time and

across geographic space, explains Professor Douglass North, who won the Nobel Prize in economic science for pioneering the study of institutional economics, “individual capturable of the benefits to society from additions to the stocks of knowledge and technology has been either absent or very imperfect. ...The profitability of investing in new knowledge and developing new techniques requires some degree of property rights over ideas and innovation. In their absence the new technology may not be forthcoming” (North, 1981:8, 10).

With patent laws governments intervene into the marketplace to provide incentives to innovators to invest their know-how, time, and money into the creation of inventions under circumstances of the “appropriability problem” associated with intangible assets (Dam, 1994:247). Without market intervention, the investment into knowledge-based innovation may be unjustifiable because the risk is great that a competitor will appropriate the invention with modest, less risky investment. However, just like prospectors staking real property claims when looking for gold, inventors stake their intellectual property claims with no guarantee that gold will be indeed their reward (Kitch, 1977). Jordanian innovators should recruit patent counsel to search the relevant “prior art” and make proper claims for patent rights, not only in Jordan but in other markets where they plan to market particular drugs, including the MENA region, Europe, and North America.

Recommendation 3c. Local pharmaceutical and bio-medical companies should manage better their trade secrets.

Jordanian companies should also focus on organizational trade secrets. A trade secret is information, under U.S. law “including a formula, pattern, compilation, program, device, method, technique, or process,” that has commercial value to a business and that the business wants to keep secret from competitors. It is a notion rooted respect for individual liberty, confidentiality of relationships, common morality, and fair competition (Paine, 1991). The law of trade secret involves more the notions of contract, trust, and equity than of property, for information maintained as a trade secret may be legally safeguarded against misappropriation but not against independent discovery or accidental leakage (Friedman, Landes, and Posner, 1991).

Jordanian pharmaceutical companies are sure to have trade secrets and, hence, need to articulate a trade secret management strategy in consultation with attorneys skilled in trade secret law and management. Clinical research organizations are especially dependent on trade secret law because their research output is data and this data is protected under “data exclusivity” provisions within trade secret law. CROs should manage their data rights carefully and be active in policy discussions regarding Jordan’s data exclusivity rules.

RECOMMENDATION 4. LOCAL AND MULTINATIONAL PHARMACEUTICAL AND BIO-MEDICAL COMPANIES IN JORDAN SHOULD CARRY-OUT

CORPORATE SOCIAL RESPONSIBILITY PROGRAMS, INCLUDING PHILANTHROPY.

International public health issues, once at the margins of international relations, media attention, and business concern, have become matters of great social and moral concern, especially with regards to developing countries. Oxfam, the advocacy and development organization, reports that 250,000 people die every *week* of infectious diseases in developing countries. HIV/AIDS threatens international public health on a scale never before seen in human history. Previous plagues and great epidemics, devastating though they were to imperial China, urbanizing Europe, and the colonizing Europe (McNeil, 1998), were regionally contained. Some 40 million people worldwide are HIV positive and AIDS has become a powerful symbol that has led health advocates to criticize the poor state of public health systems in developing countries, the failure of political leadership in these countries, in the rich countries, and at the United Nations and other multilateral organizations, and the inaction of companies in the business of public health. Many people believe that companies doing business in pharmaceuticals and bio-medical products and services have special obligations to society. The most important thing to know about the social construction of medical technology, explains public health scholar Stuart Blume (1992:3, 5), is that, because “medicine saves lives,” it is thought about quite differently from how we think about technology in general and in ways that are “anything but rational and measured.”

Jordanian companies, if they have been immune to calls for socially responsible behavior, especially in Jordan and the Middle East region, will come under increasing scrutiny. Taxi drivers tell stories about how the late King Hussein regularly listened to “talk-radio” programs in Jordan and how he would, from time-to-time when hearing a personal story of health care need, call into the program himself and encourage the person to call his office, where someone would see that the needed health care was provided despite the inability to pay. Islam imposes obligations on Muslims to, for example, give to charity (pay the zakat) and to live up to the moral duties of mercy and benevolence expressed in the Qur’an and to follow in the path of the Prophet. As Jordan continues to shift toward private sector focus and away from public sector focus, people in society will call on Jordanian companies to do more as acts of social responsibility. Jordanian companies should establish corporate social responsibility programs before these demands begin to ring loudly.

Innovative pharmaceutical companies, especially the big, rich ones, have come in recent years to find themselves under attack from public health advocates who believe their responsibilities to be great because of their patent ownership of AIDS and other important therapies. It has been explained here why intellectual property rights, including trademark, patent, and trade secret rights, should exist as a matter of economic theory but that does not fully account for their existence in social life. Intellectual property rights are social contracts implemented by the public’s representatives. The public—and, in particular, public health advocates and many in the media—seem to believe that the terms of the social contract are more than merely, “You innovate; we protect your rights for a time and so we get these wonderful innovations.” Civil society

leaders seem to be demanding that patent holders of drugs have moral responsibilities under the terms of the social contract.

AIDS is not now a crisis in Jordan and the Middle East region, according to UNAIDS. However, AIDS is a growing problem and Merck Sharp & Dohme invited and facilitated the Jordanian Ministry of Health's participation in the HIV/AIDS Accelerated Access Initiative, an international consortium composed of Boehringer Ingelheim, Bristol-Myers Squibb, Glaxo Smith Kline, Merck, Hoffman-LaRoche, UNAIDS, World Health Organization, World Bank, United Nations Children's Fund (UNICEF), and the UN Population Fund. All Merck's local employees are covered by Merck's comprehensive HIV/AIDS, Tuberculosis and Malaria Workplace Policy.

Furthermore, there are many public health problems in the country and in the region. As the World Bank has found public health standards mirror economic development and much poverty exists in the MENA region. Thus, the need for philanthropy with respect to health care is great. PhRMA has itself since 2000 carried out philanthropic acts, such as donated medicines and equipment to Jordanian health organizations associated with kidney ailments, epilepsy, and cancer. PhRMA had carried out educational programs regarding continuing physician education and erectile dysfunction disease.

Individual PhRMA-member companies have also carried out philanthropic acts. For example, Schering Plough provides Hepatitis C drugs to Jordanian patients free of charge. Aventis donated kidney dialysis machines to the government. Novartis sponsors a health clinic at Al Hussein Sports City. PhRMA and its member companies should articulate and carry-out regular corporate social responsibility programs that include acts of philanthropy.

RECOMMENDATION 5. ASSESS AND ARTICULATE STRATEGIES TO IMPROVE GOVERNMENT POLICIES AND ADMINISTRATIVE CAPACITIES REGARDING FOOD AND DRUG ADMINISTRATION, PATENT AND TRADEMARK ADMINISTRATION, AND CUSTOMS REGULATION.

The Jordan Food and Drug Administration was established in the Ministry of Health in April 2003. Dr. Salah Mawajdeh, director general of JFDA, has stated that he and his staff have been, since the JFDA's founding, revising its rules and regulations so that they are consistent with international standards. Jordan passed a clinical trial law in November 2003. As has been emphasized in this report, the clinical research organization activity is very important to Jordan and, so, the passage of the facilitating law was an important step. Drug registration is now stream-lined to a 180-day process, shorter even than the 210 process in the European Union. In general, says the director general, there has been a concerted effort to make policies and regulations better defined and more transparent.

The agency established new drug price regulations in January 2004: Each drug price is now set according to the lowest of four benchmarks: public price in country of origin, price in G7 countries, price in Saudi Arabia, and comparable local prices. It is beyond the scope of our report to assess these new regulations. However, meetings with stakeholders in Jordan for this report were conducted in February and May 2004 and many complaints were expressed about drug prices. It is clear that the price controls have a big impact on imports, exports, who is producing what and how much—essentially everything about the industry and the drug marketplace. Assessment and strategy-articulation should be carried-out regarding drug pricing in Jordan by JFDA.

Despite the director general's leadership and quick actions (and the speed—in public administration time—with which JFDA is moving is impressive), there are many complaints about JFDA. All industry components—local generic drug companies, local clinical research organizations, and multinational innovative drug companies—complain that JFDA lacks vital expertise and makes decisions both slowly and poorly as a matter of its administrative routines. Stakeholders in Jordan contended that JFDA must, but at present is not, be knowledgeable, behave according to global best practices, possess the capacity to certify bio-equivalence, Good Manufacturing Practices, Good Clinical Practices, and be respected as such by USFDA and EMEA. JFDA is a key institutional constraint on successful achievement of the Jordanian government's economic goals and on the Jordanian and locally-based multinational companies' business goals and therefore assessment and strategy-articulation for JFDA should be under-taken.

Jordan became a member of the World Trade Organization in November 1999 after a lengthy process of bringing its laws and regulations in compliance with treaty obligations of the WTO, including the TRIPS agreement, the Agreement concerning Trade-Related Aspects of Intellectual Property Rights. Jordan also acceded in 2000 to the World Intellectual Property Organization's digital copyright treaties. Jordanian law was reformed regarding data exclusivity concerning pharmaceutical and agricultural chemical R&D in order to conclude a free trade agreement with the U.S. in 2001. Most all the positive developments with respect to pharmaceuticals and bio-medical technology in Jordan identified in this report directly or indirectly owe to these policy changes of the Jordanian government.

Technology management studies show that effective patent-intellectual property rights critically enable the kinds of business relationships that Jordanian firms are increasingly establishing. Successful technology innovators seek to secure all the “complementary assets” needed to commercialize successfully their innovation. However, the technological innovator need not possess all the complementary assets in-house. Some of the essential questions of technology management concern which capabilities to possess, acquire, or build inside the organization and which capabilities to leave to a partner. When these capabilities can be gained through partnership, management scholars say that there exist “technology markets” (Arora, Fosfuri, and Gambardella, 2001). Without efficient technology markets technology innovators have either to possess, acquire, or build the complementary assets themselves—or fail in the marketplace with the new technology.

Efficient technology markets depend on effective patent rights. Vertical licensing depends on effective patent rights when the technology is to be used (or trademark rights when it is to be brand-marketed). Consider that American, European, and Japanese innovators feel sufficiently secure about their intellectual property rights in the Jordanian marketplace to pursue production and marketing relationships with local firms. Effective patent rights also crucially facilitate horizontal license technology market transactions (Arora, 1995). The parties to a licensing or cross-licensing of technology relationship look to patent rights so that the nature of the knowledge to be transferred and the terms of its use can be specified through contract (Grindley and Teece, 1997). There is currently no evidence in Jordan of technology cross-licensing relationships in the pharmaceutical and bio-medical technology sectors but they should arise in the coming years.

Efficient technology markets in the United States have fostered the existence of specialized engineering firms in industries such as chemicals, biotech, and information technology (Arora, 1997; Arora and Gambardella, 1990). These specialized firms might be thought of as pure intellectual property enterprises; rather than investing into production capabilities themselves, they license their patent rights to others with manufacturing and distribution capabilities. The university-based technology innovator that licenses a patented technology to a business enterprise is taking similar advantage of the existence of an efficient technology market. The rising CRO sub-sector is a classic example of pure intellectual property-based, specialized technology firms that owe to effective intellectual property rights. There is, however, a wrinkle in the story here because of the nature of the technology at issue. CROs conduct research that depends on the data exclusivity provisions of the law of trade secret. There are questions about data exclusivity protections as administered by the JFDA and as considered by the courts. Effective data exclusivity protections will be a necessary condition for continued development of this sub-sector.

Thus, intellectual property reforms in Jordan are crucially enabling a great deal of new business activity; business activity that is intellectual property-intensive and high value-added. Thus, Jordanians who say that patent law reform had been a big mistake for Jordan have perhaps not considered the countervailing benefits that exceed the costs of policy change. Absent the decisive patent law reform and enforcement of the past five years, few of the positive developments identified here would have taken place: The multinational companies would not be making all these R&D and marketing investments and would not be establishing production partnerships. The local Jordanian industry would still today be competing in a stagnant, no-growth Jordanian drug marketplace. Absent the commercial pressure placed on domestic firms by the governmental policy reforms, the long-term prospects for the industry would be that only forward-looking Hikma would survive while the rest would be victims of the present integrating global pharmaceutical marketplace. A number of Jordanian companies today are establishing competitive advantages for global competition, making their prospects for the future bright. The vigorous, dynamic, growing sub-sector in clinical research would still be the modest economic activity it had been. The medical tourism strategy would not be enriched by the new drugs and new medical know-how that have entered Jordan.

Pharmaceutical and bio-medical R&D and marketing requires world-class patent and trademark law and public administration. All the stakeholders interviewed for this report emphasized that the Jordanian public administration system for patents and trademarks is inadequate. Khaled Arabeyyat, the assistant director at the Industrial Property Protection Directorate of the Ministry of Industry and Trade, confirmed these critiques. Jordan has apparently decided to accede during 2005 to the Patent Cooperation Treaty and the Madrid Protocol, treaties administered by the World Intellectual Property Organization in Geneva. A master's degree in intellectual property law was established at the University of Jordan in 2002. The King Abdullah Center for Intellectual Property was established in 2002. These are important, positive steps for Jordan's intellectual property system. Assessment and strategy-articulation regarding public administration of Jordan's patent and trademark laws and cooperation among stakeholders should be under-taken.

Counterfeit, intellectual property-based products have been concentrated in software, music, films, and branded consumer goods but drugs could be a future problem (not from local manufacturers but from foreign distributors connected with unscrupulous locals selling Indian and Chinese products). Effective customs enforcement requires agents who can recognize counterfeit drugs and packages, who have world-class search-and-seizure capacities, and who are supported by prosecutorial and judicial authorities. Structures, processes, and human capacities should be assessed and strategy should be articulated for optimum functioning with respect to customs enforcement.

RECOMMENDATION 6. ASSESS AND ARTICULATE STRATEGIES TO IMPROVE UNIVERSITY AND PUBLIC SCIENCE AND TECHNOLOGY RESEARCH AND ENCOURAGE TECHNOLOGY TRANSFER TO AND COMMERCIALIZATION BY THE PRIVATE SECTOR.

Local and multinational industry praises the local universities for providing them with competent, educated employees. However, they also criticize that the university and public R&D system in Jordan is as largely disengaged from business and industry in general, and bio-medical business and industry in particular. They contend that neither the universities nor the Royal Scientific Society, Jordan's primary public research institution, appear to be sufficiently focused on applied research and technology commercialization. Jordanian leaders should consider alternative US national innovation models, including the MIT/Stanford model and the NIH/NSF/national laboratories model, and these models should be contrasted with the German Max Planck model and the Japanese industry-dominant model. The universities, the RSS, the Higher Council for Science and Technology, the various high-tech incubators, the King Hussein Medical Center and other hospitals should be assessed for their roles in the system.

It appears that the research institutions should establish policies, practices, and organizational capabilities within the universities and public laboratories that encourage the commercialization of technology, including patent rights, royalty and other incentives, and technology transfer offices. It appears that what is needed is the construction of a US Bayh-Dole system including laws that grant patent rights to universities and public laboratories. Assessment and strategy articulation regarding the university and public science and technology institutional setting in Jordan should be under-taken.

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